

AMENDMENTS TO THE CLAIMS

1. (Cancelled)

2-4. (Cancelled)

5-6. (Cancelled)

7-9. (Cancelled)

10-13. (Cancelled)

14-15. (Cancelled)

16. (Withdrawn - Currently Amended) The composition for solubilization of paclitaxel according to ~~Claim 13~~ claim 85,

wherein the calcium channel blocker is chosen from verapamil and a dihydropyridine chosen from nifedipine, nicardipine and nitrendipine; wherein the calmodulin antagonist is chosen from trifluoroperazine; wherein the antihypertensive is reserpine; wherein the Vinca alkaloid is chosen from vincristine and vinblastine; wherein the steroid is progesterone; wherein the antiarrhythmic is chosen from amiodarone and quinidine; wherein the anthelmintic is chosen from quinacrine and quinine; and wherein the immunosuppressant is chosen from cyclosporine A, staurosporine and tacrolimus.

17-26. (Cancelled)

27. (Cancelled)

28. **(Withdrawn - Currently Amended)** A method of preparing the composition for solubilization of paclitaxel according to ~~Claim 1~~ claim 78, wherein said method comprises the steps of:

(1) solubilizing ~~4-99~~ 40 to 89.9% by weight of monoolein in ~~0.01-99~~ 10 to 59.9% by weight of an oil chosen from triglyceride, iodized oil, vegetable oil and animal oil ~~so that the ratio of monoolein to oil is more than 1:1~~; and

(2) solubilizing completely ~~0.01-20~~ 0.01 to 10% by weight of paclitaxel in said mixture in step (1) by stirring.

29-77. **(Cancelled)**

78. **(Currently Amended)** A solubilized paclitaxel composition consisting essentially of:

- 1) 40 to 89.9% by weight of monoolein;
- 2) 10 to 59.99% by weight of an oil chosen from triglyceride, iodized oil, vegetable oil and animal oil; and
- 3) 0.01 to 10% by weight of paclitaxel.

79. **(New)** A solubilized paclitaxel composition consisting essentially of:

- 1) 40 to 89.9% by weight of monoolein;
- 2) 10 to 59.99% by weight of an oil chosen from triglyceride, iodized oil, vegetable oil and animal oil; and
- 3) 0.01 to 10% by weight of paclitaxel; and
- 4) 0.01 to 5 % by weight of additive, wherein the additive is selected from the group consisting of an anticancer drug, a p-glycoprotein and a hepatic metabolism blocker.

80. (New) A solubilized paclitaxel composition consisting essentially of:
- 1) 40 to 89.9% by weight of monoolein;
 - 2) 10 to 59.99% by weight of an oil chosen from triglyceride, iodized oil, vegetable oil and animal oil;
 - 3) 0.01 to 10% by weight of paclitaxel; and
 - 4) 0.01 to 90% by weight of at least one emulsifier.
81. (New) The solubilized paclitaxel composition according to any one of claims 78 to 80,
- wherein said triglyceride is chosen from saturated and unsaturated triglycerides having 2 to 20 carbon atoms in each hydrocarbon chain.
82. (New) The solubilized paclitaxel composition according to any one of claims 78 to 80,
- wherein said triglyceride is chosen from triacetin, tributyrin, tricaproin, tricaprylin, tricaprin and triolein;
- wherein said iodized oil is chosen from Lipiodol, iodized poppy seed oil, Ethiodol and iodized soybean oil;
- wherein said vegetable oil is chosen from soybean oil, cottonseed oil, olive oil, poppyseed oil, linseed oil and sesame oil; and
- wherein said animal oil is chosen from squalane and squalene.
83. (New) The solubilized paclitaxel composition according to any one of claims 78 to 80,
- wherein the composition is suitable for oral administration, buccal administration, mucosal administration, intranasal administration, intraperitoneal administration, subcutaneous injection, intramuscular injection, transdermal administration, or intratumoral injection.

84. (New) The solubilized paclitaxel composition according to any one of claims 78 to 80,

wherein the composition is liquid or semi-solid state at room temperature.

85. (New) The solubilized paclitaxel composition according to claim 79,

wherein the anticancer drug is chosen from doxorubicin, cisplatin, carboplatin, carmustin (BCND), dacarbazine, etoposide, 5-fluorouracil and a paclitaxel derivative chosen from docetaxel, bromotaxel and taxotere; wherein said p-glycoprotein inhibitor is chosen from cinchonin, a calcium channel blocker, a calmodulin antagonist, an antihypertensive, a Vinca alkaloid, a steroid, an antiarrhythmic, an anthelmintic and an immunosuppressant; and wherein said hepatic metabolism blocker is chosen from an anticancer drug chosen from cyclosporin A, doxorubicin, etoposide (VP-16) and cisplatin, verapamil and tamoxifen.

86. (New) The solubilized paclitaxel composition according to claim 80,

wherein said emulsifier is chosen from a phospholipid, a non-ionic surfactant, an anionic surfactant, a cationic surfactant and bile acid.

87. (New) The solubilized paclitaxel composition according to claim 86,

wherein said phospholipid is chosen from a phosphatidylcholine (PC) and its derivative, a phosphatidylethanolamine (PE) and its derivative, a phosphatidylserine (PS) and its derivative, and a polymeric lipid wherein a hydrophilic polymer is conjugated to the lipid headgroup;

wherein said non-ionic surfactant is chosen from a poloxamer (polyoxyethylene-polyoxypropylene copolymer), a sorbitan ester (sorbitan esters), a polyoxyethylene sorbitan and a polyoxyethylene ether;

wherein said anionic surfactant is chosen from a phosphatidylserine (PS) and its derivative, a phosphatidic acid (PA) and its derivative, and sodium dodecyl sulfate (SDS);

wherein said cationic surfactant is chosen from 1,2-dioleoyl-3-trimethylammonium propane (DOTAP), dimethyldioctadecylammonium bromide (DDAB), N-

[1-(1,2-dioleloxy)propyl]-N,N,N-trimethylammonium chloride (DOTMA), 1,2-dioleyl-3-ethylphosphocholic acid (DOEPC) and 3β -[N[(N',N'-dimethylamino)ethan]carbarnoyl] cholesterol (DC-Chol); and

wherein said bile acid is chosen from cholic acid, its salt and derivatives; deoxycholic acid, its salt and derivatives; chenocholic acid, its salt and derivatives; and lithocholic acid, its salt and derivatives.

88. (New) The solubilized paclitaxel composition according to claim 78, consisting of:

- 1) 40 to 89.9% by weight of monoolein,
 - 2) 10 to 59.99% by weight of an oil chosen from triglyceride, iodized oil, vegetable oil and animal oil, and
 - 3) 0.01 to 10% by weight of paclitaxel,
- wherein the solubilized paclitaxel composition is a lipid-based oral formulation.

89. (New) The solubilized paclitaxel composition according to claim 79, consisting of:

- 1) 40 to 89.9% by weight of monoolein,
 - 2) 10 to 59.99% by weight of an oil chosen from triglyceride, iodized oil, vegetable oil and animal oil, and
 - 3) 0.01 to 10% by weight of paclitaxel, and
 - 4) 0.01 to 5 % by weight of additive, wherein the additive is selected from the group consisting of an anticancer drug, a p-glycoprotein and a hepatic metabolism blocker, and
- wherein the solubilized paclitaxel composition is a lipid-based oral formulation.

90. (New) The solubilized paclitaxel composition according to claim 80, consisting of:

- 1) 40 to 89.9% by weight of monoolein,

2) 10 to 59.99% by weight of an oil chosen from triglyceride, iodized oil, vegetable oil and animal oil,

3) 0.01 to 10% by weight of paclitaxel, and

4) 0.01 to 90% by weight of at least one emulsifier,

wherein the solubilized paclitaxel composition is a lipid-based oral formulation.

91. (New) The solubilized paclitaxel composition according to any one of claims 78 to 80, wherein the solubilized paclitaxel composition is dispersed in water.